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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,184	10/03/2003	J.H. David Wu	176/61411 (2-11141-03010)	2775
7590 08/01/2006			EXAMINER	
Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051			BELYAVSKYI, MICHAIL A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,184

Applicant(s)

WU ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) 31-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-120 are pending.

2. Applicant's election with traverse of Group I, claims 1-23 in the reply filed on 05/25/06 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the search of all Groups together would not constitute a serious search burden on the examiner and that search of the claims of Group I would provide useful information for the claims of other Groups

This is not found persuasive because the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria and therefore establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in paragraphs 3-5 of the previous Office Action and above

The requirement is still deemed proper and is therefore made FINAL.

3. Upon further consideration, the prior art search has been extended to include claims 24-30 of Group II.

Claims 31-120 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-30 drawn to a method of culturing peripheral lymphoid organ cells comprising culturing said cells on a three-dimensional scaffolding are under consideration in the instant application.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 22 and 23 being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is method step: it is unclear if cells were isolated and reseeded into the new culture medium or if cells with old culture medium were reseeded. Also it is unclear if reseeded step require three-dimensional matrix.

The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-30 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/036589 (IDS).

WO'589 teaches a method of culturing peripheral lymphoid organ cells on a three-dimensional scaffolding which is covered with culture medium (see entire document, Abstract and page 3 in particular). WO'589 teaches a culture medium comprising growth factors and cytokines, for example IL-2 or IL-4 (see pages 4 and 17 in particular). WO'589 teaches a method of producing antigen-specific T cells, comprising culturing T cells with antigen, wherein said antigen is presented by APC (see pages 5 – 6, and 22 in particular). WO'589 teaches that said antigen is a tumor antigen (see page 22 in particular). WO'589 teaches that three-dimensional structure formed from different porous particles and material including ceramic (see pages 15 and 16 in particular).

Claims 19 and 20 are included because the claimed functional limitation would be inherent properties of the referenced method of culturing cells. It is noted that the referenced and claimed method using the same culturing conditions. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then

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the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention.

9. Claims 1-7 and 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/15629 or US Patent 5,160,490 (IDS)

WO' 629 teaches a method of culturing cells, including T lymphocytes on a three-dimensional scaffolding which is covered with culture medium (see entire document, Abstract and page 4, 15 and 28 in particular). WO'629 teaches that three-dimensional structure formed from different porous particles and material including ceramic (see pages 7 and 9 in particular). WO' 629 teaches a culture medium comprising growth factors and cytokines (see page 12 in particular). WO' 629 teaches that culturing cells in three-dimensional matrix allows cells to have cell-cell contact in the three dimensions and is beneficial for growth and maintenance of cell culture (see page 4 in particular).

US Patent '490 teaches a method of culturing cells, including T lymphocytes on a three-dimensional scaffolding which is covered with culture medium (see entire document, Abstract and columns 5 and 9 in particular). US Patent '490 teaches that three-dimensional structure formed from different porous particles and material including ceramic (see columns 9 and 10 in particular). US Patent '490 teaches a culture medium comprising growth factors and cytokines (see column 13-14, 16 in particular). WO' 629 teaches that culturing cells in three-dimensional matrix allows cells to have cell-cell contact in the three dimensions and is beneficial for growth and maintenance of cell culture (see column 9 and 10 in particular).

Claims 19 and 20 are included because the claimed functional limitation would be inherent properties of the referenced method of culturing cells. It is noted that the referenced and claimed method using the same culturing conditions. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The references teaching anticipates the claimed invention.

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 6, 8-12 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/15629 or US Patent 5,160,490 (IDS) in view of US Patent 6,821,778

The teaching of WO 99/15629 or US Patent 5,160,490 has been discussed, supra.

The claimed invention differs from the reference teaching in that WO 99/15629 or US Patent 5,160,490 does not explicitly teach a method of culturing lymphoid organ cells on a three-dimensional matrix in the medium containing an antigen that is presented by antigen presenting cells.

US Patent '778 teaches a method of producing an antigen-specific lymphocyte, comprising culturing T cells in the medium with antigens that are presented by antigen presenting cells (see entire document, Abstract in particular). US Patent '778 teaches that various types of antigens including tumor antigens that can be presented by APC (see column 10 in particular). US Patent '778 teaches that obtained antigen-specific lymphocytes can be used for various uses, including immunotherapy (see column 5 in particular).

US Patent '378 teaches a method of producing an antigen-specific lymphocyte, comprising culturing T cells in the medium with antigens that are presented by antigen presenting cells (see entire document, Abstract in particular). US Patent '378 teaches that various types of antigens including tumor antigens that can be presented by APC (see column 14-15 in particular). US Patent '778 teaches that obtained antigen-specific lymphocytes can be used for various uses, including immunotherapy (see column 7 in particular).

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '778 and US Patent '378 to those of WO 99/15629 or US Patent 5,160,490 to obtain a claimed method of producing an antigen-specific lymphocytes, comprising culturing lymphoid organ cells on a three-dimensional matrix in the medium containing an antigens that are presented by antigen presenting cells.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because culturing lymphocytes in the medium containing antigens , wherein said antigens are presented by APC would generate an antigen-specific lymphocytes that can be used for various treatment, including immunotherapy as taught by US Patent '778 and US Patent '378. Culturing said lymphocytes and APC can be done on a three-dimensional matrix which is covered with culture medium, as taught by WO 99/15629 or US Patent 5,160,490 . The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Semaker*, 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-120 of copending Application No. 20050191743 and claims 1-106 of copending Application No. 20030109042. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-120 of copending Application No. 20050191743 and 1-106 of copending Application No. 20030109042 each recites a method of culturing lymphocytes, comprising culturing said lymphocytes on a three-dimensional matrix in the presence of antigens presented by APC in the medium comprising growth factors or cytokines.

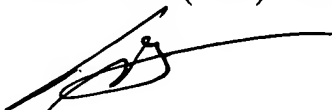
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKIY, PH.D.
PATENT EXAMINER

7/28/06